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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,400	12/20/2001	Diana Zanini	VTN-568	3607

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EXAMINER

CHOI, FRANK I

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 03/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/028,400

Applicant(s)

ZANINI ET AL.

Examiner

Frank I Choi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) 25-72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☒ Claim(s) 18-24 is/are objected to.
- 8) ☒ Claim(s) 1-72 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-54, drawn to an antimicrobial lens comprising silver and a polymer comprising a monomer of formulas I-IV.
- II. Claims 55-59, drawn to a method of producing an antimicrobial lens comprising silver and a polymer comprising a monomer of formulas I-IV.
- III. Claims 60, 61, drawn to an antimicrobial lens comprising silver and a polymer comprising a binding monomer which can reversibly bind silver.
- IV. Claim 62, drawn to a lens case comprising silver and a polymer comprising a monomer of formulas I-IV.
- V. Claim 63, drawn to a method of reducing the adverse effects associated with microbial production in the eye of a mammal comprising providing an antimicrobial lens comprising silver and a polymer comprising a monomer of formulas I-IV.
- VI. Claims 64-72, drawn to an antimicrobial lens comprising silver having sufficient movement in the eye of a patient and/or inhibits microbial production by at least 25%.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, III and VI are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be

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separately usable. In the instant case, inventions I, III, VI have separate utility in that each do not appear to require the particulars of the other for patentability. See MPEP § 806.05(d).

Inventions II and I, III and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the products as claimed can be made by another and materially different process as evidenced by the fact that inventions III and VI do not require the claimed polymers of Invention II.

Inventions I, III, and VI and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process for using the product as claimed can be practiced with another materially different product as evidenced by the fact that inventions III and VI do not require the claimed polymers of Invention V.

Inventions II and V are related as process of making and process of using the product. The use as claimed can be practiced with a materially different product and products as claimed can be made by another and materially different process. Since the product is not allowable, restriction is proper between said method of making and method of using. (MPEP § 806.05(i)).

Inventions IV and I-III, V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

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operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions as Invention IV is a case for storage of contact lens and cannot be used in the eye whereas Inventions I-III, V and VI are directed to contact lens, preparation thereof and use thereof.

Because these inventions are distinct for the reasons given above and the following:

The search required for Group II is not required for Groups I, III-VI in that a process of making need not be searched, the search for Group III is not required for Groups I, II, IV-VI in that the reversible binding to silver need not be searched, the search for Group IV is not required for Groups I-III, V, VII in that a contact lens cases need not be searched, the search for Group V is not required for Groups I-IV, VI in that the used of the product need not be searched, and the search for Group VI is not required for Groups I-V in that the movement of the lens on the eye and/or the percent of microbial formation need not be searched, restriction for examination purposes as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable as follows: If either Groups I, II, IV, V are elected, Applicant is directed to elect a single disclosed species of the monomer represent by formulas I, II, III or IV. If Group III is elected, Applicant is directed to elect a single disclosed species of a binding monomer. If Group VI is elected no election of species is required.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Karen Harding on 3/7/2003, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-54 and a monomer of Formula I, N,N'-(bisacryloyl)cystamine (CYST). Affirmation of this election must be made by applicant in replying to this Office action. During the course of prosecution of the elected species in relation to the elected Group I, it appears that an antimicrobial contact lens comprising silver and a polymer comprising the CYST monomer may be allowable. As such, the elected species was expanded to include all of Formula I. As such, Claims 25-72 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

Claims 18-24 are objected to as being dependent upon a rejected base claim, but may be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Examiner notes that Applicant may satisfy the requirement of including all of the limitations of the base claim without having to repeat the entire listing of all of the monomers of Formulas I-IV. For example "An antimicrobial lens comprising silver and a polymer comprising the monomer [insert the formula of CYST], wherein the lens is a silicone hydrogel. Alternatively, if Applicant wishes to retain the "Formula I" language, Applicant could set out Formula I and the specific definitions of the variables which would define the monomer CYST.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2,4-9,14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 05-269181.

JP 05-3269181 expressly discloses an antimicrobial soft contact lens comprising 69.7 w% 2-hydroxyethyl methacrylate, 24.6 w% methyl methacrylate, 0.4 w% ethylene glycol dimethacrylate and 5w% silver acrylacetate or 5w% silver benzoyl acetate (paragraphs 0052-0055). The rejection is based on an interpretation of the limitation “about” to include amounts greater than the specifically set forth range, including amount expressly disclosed in the prior art.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over by JP 05-269181 in view of the acknowledged prior art, Vanderlaan et al. (US Pat. 5,998,498), Laskey (US Pat. 3,929,741).

JP 05-3269181 teaches an antimicrobial soft contact lens comprising an antimicrobial substance, such as an acrylacetate or benzoyl acetate complex of silver, ranging from 0.1 to 20% by weight, polymers of monomers, including methacrylic and acrylic esters, siloxanyl alkyl (meta) acrylate, carboxylic acid vinyls, acrylic acid, methacrylic acid, methyl methacrylate, hydroxyethyl methacrylate, dimethyl acrylamide, glycol acrylates and glycol methacrylates (paragraphs 0009-0012, 0024-0027). Specific examples of soft contact lenses are taught containing

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69.7 w% 2-hydroxyethyl methacrylate, 24.6 w% methyl methacrylate, 0.4 w% ethylene glycol dimethacrylate and 5w% silver acrylacetate or 5w% silver benzoyl acetate (paragraphs 0052-0055). It is taught that the amount of the antibacterial substance to be added depends on the maintenance of transparency and antimicrobial activity (paragraph 0028).

Applicant acknowledges that soft contact lenses based on hydrogels are widely used because they are more comfortable but that extended use encourages the build of bacteria and other microbes (Pg. 1). It is acknowledged that examples of these soft contact lens, include etafilcon A, balafilcon A, aquafilcon A, lenefilcon, lotrafilcon and silicone hydrogels (Pg. 20, lines 1-8).

Vanderlaan et al. teach that soft contacts can be prepared from silicone hydrogels which combine silicone containing monomers and hydrophilic monomers (See entire reference, especially column 5).

Laskey teaches that hydrophilic monomers of acrylamido sulfonic acid or sulfonate are suitable for soft contact lenses and have greater water retention and because of a greater ability for cross-linking have increased flexibility in the modification of physical properties (Column 1).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose an antimicrobial contact lens comprising silver and a polymer comprising a monomer of formula I in which R3 being substitute phenyl, the claimed organic sulfonic acid, organic phosphoric acid or organic disulfide, or the lens is etafilcon A, balafilcon A, aquafilcon A, lenefilcon, lotrafilcon or silicone hydrogel. However, the prior art amply suggests the same as antimicrobial soft contact lenses containing silver and monomers falling within the scope of formula I are known in the art. As such, it would have been well within the skill of and one of

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ordinary skill in the art would have been motivated to modify the prior art as above with the expectation the soft contact lenses produced would have antimicrobial properties and, thus, avoid the problems associated with extended wear.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion


A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC

March 8, 2003


JOHN PAK
PRIMARY EXAMINER
GROUP 1600

